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10/575,562	04/12/2006	Masato Shirai	KUZ0029US.NP	1387

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EXAMINER

ORWIG, KEVIN S

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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04/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/575,562	Applicant(s) SHIRAI ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan. 29, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments and arguments filed Jan. 29, 2009 are acknowledged and have been fully considered. Claims 1-7 are amended (the text of claims 1 and 4 has been amended; claims 2-3 and 5-7 are amended via their dependency on claim 1).

The objection to claim 1 is withdrawn in light of the claim amendments.

The rejection of claims 1-7 under 35 U.S.C. 112, 2nd paragraph is withdrawn, in light of the claim amendments.

The rejection of claims 1-7 under 35 U.S.C. 103(a) is maintained as discussed below.

No new grounds of rejection are set forth below.

Claim Objections

Claims 1 is objected to because of the following informalities: the recitation, "...comprises three ingredients of polyisoprene..." is awkward. The clarity of the claim language would be improved by adding a colon or semicolon after the word "ingredients", deleting the article "of", and delineating each the three components (polyisoprene, a styrene/isoprene/styrene copolymer, and solid polyisobutylene) with a line indentation and/or a reference character (i.e. a), b), and c)).

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1611

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over LIPMAN (U.S. 2004/0243042; Filed May 20, 2003) as evidenced by YANO (U.S. 5,556,636; Issued Sep. 17, 1996) and by TABAR (U.S. 4,419,480; Issued Dec. 6, 1983).

1. A large body of literature exists regarding pressure-sensitive adhesive compositions comprising the components claimed in instant claim 1. For instance, it is

Art Unit: 1611

known that plasters and other medical adhesives are commonly prepared from, *inter alia*, styrene-isoprene-styrene block copolymers, polyisobutylene, and polyisoprene, and that tackifiers and other softening agents are added to impart a pressure-sensitive adhesion property to these compositions (see Yano column 1, lines 21-34). Thus, each of the components recited in claim 1 was well-known in the art at the time of the invention.

2. Lipman discloses compositions comprising pressure-sensitive adhesives (abstract; paragraphs [0034] and [0035]). Lipman teaches adhesive compositions comprising high molecular weight polyisobutylene (i.e. solid polyisobutylene) (paragraph [0051]; Table at bottom of page 10 and top of page 11) along with polyisoprene and styrene-isoprene-styrene (SIS) copolymers (Table at bottom of page 10 and top of page 11, wherein Kraton D-1161 is a SIS copolymer). Additionally, the adhesive compositions taught by Lipman comprise a liquid rubber component (paragraphs [0009] and [0051]) and a tackifier (paragraph [0070]). The liquid rubber component may be a low molecular weight polyisobutylene (paragraph [0070], see page 7, left column, lines 1-3).

3. Lipman teaches the components of the adhesive compositions in the proportions claimed in instant claim 1. For instance, the adhesives of Lipman are present in an amount from about 10% to 80% of the composition (paragraph [0033]). It is noted that the adhesives can be *one or more of, inter alia*, polyisoprene, styrene-isoprene-styrene polymers, and polyisobutylene (paragraph [0034]). Relative to 100% total weight of the composition, the percentages taught by Lipman represent "parts" (e.g. 1% equals 1

Art Unit: 1611

part). Based on this evidence and reasoning, Lipman teaches each of polyisoprene, styrene-isoprene-styrene, and polyisobutylene (i.e. solid polyisobutylene) in proportions that may be from about 10% to 80% of the composition (i.e. 10-80 parts). For instance, the teachings of Lipman indicate that these components may be present in amounts, for example, of 10 parts polyisoprene, 20 parts styrene-isoprene-styrene copolymer, and 30 parts solid isobutylene (paragraphs [0034] and [0051]).

4. Lipman also teaches the inclusion of liquid polyisobutylene (paragraph [0070]) in a range from 1-30 parts relative to the total of the other three components. For instance, the isobutylene could be present in an amount of 10% (i.e. 10 parts), for example. In this case, 10 parts liquid isobutylene corresponds to about 17 parts relative to the other three components when they are present in the proportions discussed above (e.g. 10 parts polyisoprene, 20 parts styrene-isoprene-styrene copolymer, and 30 parts solid isobutylene, for a total of 60 parts). Since Lipman also teaches the use of tackifiers, each element of instant claim 1 is taught in the prior art. However, the difference between Lipman and the instant claims is that Lipman does not explicitly embody the claimed invention with sufficient specificity to be anticipatory.

5. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine all the ingredients as instantly claimed based on the teachings of Lipman to produce the instant invention. As noted above, each of the instantly claimed components of the adhesive composition is well known in the adhesive arts. Furthermore, Lipman teaches that the polyisoprene, styrene-isoprene-styrene copolymer, and isobutylene adhesive components are

Art Unit: 1611

equivalent and interchangeable (paragraph [0034]; see table at bottom of page 10 and top of page 11, wherein each of the claimed adhesive components are used, often in combination, to prepare an adhesive composition for the same purpose).

6. It is noted that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See MPEP § 2144.06. Furthermore, the MPEP states that the selection of known materials based on their suitability for their intended uses is also *prima facie* obvious. See MPEP § 2144.07. In the instant case, applicants are claiming a combination of known ingredients for the same purpose as that which has been taught in the art. Thus, in light of the teachings of Lipman, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine all the ingredients as instantly claimed based on the teachings of Lipman to produce an adhesive composition, reading on instant claim 1.

7. The high molecular weight polyisobutylene taught by Lipman (paragraph [0108]) has a viscosity average molecular weight of not less than 900,000 (see Tabar *et al.* column 8, lines 30-35), reading on instant claim 2.

Art Unit: 1611

8. Lipman discloses two embodiments wherein the low molecular weight polyisobutylene has a viscosity average molecular weight of not more than 70,000 (paragraph [0061]), reading on instant claim 3.

9. Lipman teaches the use of tackifiers resins including, *inter alia*, rosin, terpene, and phenol types (paragraph [0070]), reading on instant claim 5.

10. Lipman teaches that the adhesive layer further comprises at least one moisturizing agent (paragraph [0088]; claim 15). These agents include percutaneously absorbable compounds such as squalene and lecithin (paragraph [0088]). Squalene, for example, is a known skin-penetrating agent that can be used to treat various skin disorders such as dry skin, psoriasis, and eczema. Thus, these agents can be considered drugs as defined in the instant specification (paragraph [0030]), reading on instant claim 6.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipman in view of KUNIYA (U.S. 2002/0045043; Published Apr. 18, 2002).

11. Lipman teaches the pressure-sensitive adhesive composition of instant claim 1 as applied above. Lipman does not teach the tackifier in a proportion of 10-80 parts by weight. Further, while Lipman teaches the pressure-sensitive adhesive composition adhered to a fluid absorbing layer and a moldable adhesive layer (paragraph [0092] and Figure 4), Lipman does not teach the adhesive composition laminated on a backing and covered with a liner.

12. Kuniya discloses pressure-sensitive adhesive compositions comprising a solid rubber component and a liquid rubber component (abstract). The adhesive composition of Kuniya comprises components of instant claim 1, including styrene-isoprene-styrene copolymers (paragraphs [0016] and [0017]) in combination with other isoprene polymers, such as styrene-isoprene copolymers, which are a type of polyisoprene (paragraph [0018]). Kuniya further teaches the use of a liquid rubber component such as polyisobutylene (paragraph [0019]) and tackifiers (paragraphs [0021] and [0022]).

13. Kuniya teaches the inclusion of the tackifier in an amount from 25-80 parts by weight based on the total amount of the other rubber components in the adhesive composition (abstract). Kuniya teaches that using a high proportion of tackifier improves the adhesion force of the composition (paragraph [0009]). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a high proportion of tackifier in the compositions taught by Lipman, in order to

Art Unit: 1611

improve the adhesive force of the composition as taught by Kuniya, reading on instant claim 4.

14. Kuniya teaches laminating the adhesive composition of their invention to a backing film (paragraph [0014]; claim 7), which may be one of a plurality of such films (paragraph [0028]). Furthermore, Kuniya teaches that the backing may be lined with polypropylene tape (i.e. a liner) (paragraph [0054]). As stated above, Lipman teaches applying the adhesive composition to a backing (paragraph [0092]; figures 4 and 5). In light of the teachings of Kuniya, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to laminate the adhesive composition of Lipman onto a backing, which is covered by a liner. One would have been motivated to do so to produce a marketable final product comprising the adhesive composition, such as the pressure-sensitive adhesive sheets of Kuniya, reading on instant claim 7.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the compositions of Lipman and those of the instant invention are not useful for the same purpose (page 9 of the response).

Applicants state that Lipman is directed to facial masks for use in wound management and further state that Lipman does not teach that their compositions provide favorable tackiness irrespective of whether the temperature of the surrounding air is high or low, long term storage stability, retain the necessary cohesive force, and do not irritate the skin. The examiner notes that none of these characteristics appear in the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tackiness at various temperatures, stability, skin irritation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Lipman does not teach certain features of the invention (which are not claimed), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Art Unit: 1611

By attempting to distinguish the intended use of the pressure sensitive adhesives of Lipman from those instantly claimed, applicants appear to be arguing that Lipman is nonanalogous art. In response to applicant's argument that Lipman is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lipman is not only highly pertinent to the particular problem addressed in the instant application, but is in the field of applicants' endeavor.

Firstly, while Lipman is concerned with facial masks, these structures are compositions comprising pressure-sensitive adhesives, which can be used for the same purpose as the pressure sensitive adhesives of the instant application. Lipman's disclosure devotes considerable effort to the description of the pressure sensitive adhesives, which contain all of the instantly claimed components as discussed in the prior Office action. The ordinary artisan would appreciate that the adhesives disclosed by Lipman could be used for any related medical application and would not be limited solely to facial masks. Secondly, the instant application is drawn to pressure sensitive adhesive that can be used for a surgical dressing for wound management (instant paragraphs [0045]), just as those of Lipman. Thirdly, while Lipman is silent as to the characteristics of tackiness at various temperatures, stability, skin irritation, there is nothing in Lipman to suggest that Lipman's compositions would fail to meet these limitations. In fact, a pressure sensitive adhesive meeting all of these limitations would

Art Unit: 1611

appear to be ideal for use in Lipman's facial masks. Thus, the two disclosures are highly related and can be considered to be in the same field of endeavor, namely the development of pressure sensitive adhesives for biomedical use.

Applicants argue that the cited combination of references do not expressly teach or suggest all of the components as instantly claimed (page 9-10 of the response). Applicants' arguments have been fully considered but are not persuasive.

As stated in the prior Office action, Lipman teaches each element of instant claim 1. However, the difference between Lipman and the instant claims is that Lipman does not explicitly embody the claimed invention with sufficient specificity to be anticipatory. It is precisely the lack of an *express teaching* by Lipman which caused the rejection to be made under obviousness rather than anticipation. It is noted that express teachings are not the standard for obviousness rejections. The examiner disagrees with applicants' assertion that there is no suggestion in the prior art of the instantly claimed invention. Rather, the entire prior Office action, in which a *prima facie* case of obviousness was established, set forth precisely how the prior art suggests the instantly claimed invention.

Applicants argue that the instant invention possesses unexpected properties. Applicants further assert that the alleged unexpected results overcome the *prima facie* case of obviousness (page 11 of the response). Applicants' arguments have been fully considered but are not persuasive.

Art Unit: 1611

Applicants direct the examiner's attention to pages 17-31 of the specification (paragraphs [0051]-[0080] of the pre-grant publication). Applicants have constructed 12 examples representing various combinations of the 5 main components (as recited in instant claim 1) of the instant invention. Applicants have provided 4 comparative examples. The difference between Examples 1-12 and the 4 comparative examples is that the comparative examples do not contain the liquid rubber component (i.e. non-solid isobutylene polymer). The data presented are insufficient to overcome the rejection for several reasons.

The data presented are largely qualitative and appear to be highly subjective. The specific method by which the "Finger Tack" study was carried out was not described. Furthermore, it is stated that the "Finger Tack", "Stickiness Test When Sweating", and "Stickiness Test When Having a Bath" were conducted with "subjects", but it is not clear whether these were impartial volunteers or how the patches were administered on each subject in order to maintain an *objective measure* of each adhesive composition. It is noted that not all of the comparative examples were evaluated in all of the tests. The only objective data presented (i.e. Probe Tack and 180° Removal) do not include standard errors, and are no different for the comparative examples than for Examples 1-9 to which they are compared. Furthermore, instant paragraphs [0072] and [0073] support the finding that the tackiness for the comparative examples is similar to, if not better than, Examples 1-9.

It is only the subjective data that show any difference between the instant and comparative compositions. If, *in arguendo*, the subjective data are taken at face value,

Art Unit: 1611

irrespective of the above issues, at best these data demonstrate that the addition of the non-solid isobutylene polymer to the other components results in an adhesive composition with increased tackiness relative to compositions lacking this component. This demonstration cannot be considered "unexpected". For example, Lipman teaches that the polyisobutylene component is a permanently tacky component that can be added to the compositions to modify tack and optimize adhesion properties (paragraphs [0034], [0052], and [0070]). Additionally, Kuniya teaches that the combination of a solid rubber, a liquid rubber (such as polyisobutylene), and a tackifier can improve the low-temperature characteristics and increase the adhesion of the adhesive compositions (paragraphs [0021] and [0022]). Furthermore, it was well-known in the art at the time of the invention that polyisobutylenes having a viscosity average molecular weight of not more than 70,000 in pressure sensitive adhesives function to provide adhesion and hold the composition together. As evidence of the state of the art, see Doyle (U.S. 4,551,490; Issued Nov. 5, 1985) at column 2, line 65 to column 3, line 3. In light of these teachings, an ordinary artisan would fully expect that adding non-solid polyisobutylenes to a pressure sensitive adhesive composition would increase the overall tackiness and adhesive properties of the composition. Thus, the data showing an increase in adhesion/tackiness following the addition of non-solid polyisobutylene to pressure sensitive adhesives cannot be considered unexpected and the data provided in the specification are insufficient to overcome the rejections of record.

Summary/Conclusion

Claim 1 is objected to; claims 1-7 are rejected.

Art Unit: 1611

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643